



**Sterne Kessler  
Goldstein Fox**  
ATTORNEYS AT LAW

Robert Greene Sterne  
Edward J. Kessler  
David K.S. Comwell  
Robert W. Esmond  
Tracy-Gene G. Durkin  
Michele A. Cimbala  
Michael B. Ray  
Robert E. Sokohl  
Eric K. Steffe  
Michael Q. Lee  
Steven R. Ludwig  
John M. Covert  
Linda E. Alcom  
Robert C. Millonig  
Lawrence B. Bugaiksy  
Donald J. Featherstone  
Michael V. Messinger

Judith U. Kim  
Timothy J. Shea, Jr.  
Patrick E. Garrett  
Heidi L. Kraus  
Edward W. Yee  
Albert L. Ferro\*  
Donald R. Banowitz  
Peter A. Jackman  
Molly A. McCall  
Teresa U. Medler  
Jeffrey S. Weaver  
Kendrick P. Patterson  
Vincent L. Capuano  
Eldora Ellison Floyd  
Thomas C. Fiala  
Brian J. Del Buono  
Virgil Lee Beaston\*  
Kimberly N. Reddick

Theodore A. Wood  
Elizabeth J. Haanes  
Bruce E. Chalker  
Joseph S. Ostroff  
Frank R. Cottingham  
Christine M. Uhler  
Rae Lynn Prengaman  
Jane Shereshovitch\*  
Lawrence J. Carroll\*  
George S. Bardmessner  
Daniel A. Klein\*  
Rodney G. Maze  
Jason D. Eisenberg  
Michael D. Specht  
Andrea J. Kamage  
Tracy L. Muller  
Jon E. Wright\*  
LuAnne M. Yuricek\*

John J. Figueira  
Ann E. Summerfield  
**Registered Patent Agents\***  
Karen R. Markowicz  
Nancy J. Leith  
Helene C. Carlson  
Gaby L. Longsworth  
Matthew J. Dowd  
Aaron L. Schwartz  
Angeline G. Uy  
Mary B. Tung  
Katrina Y. Pei  
Bryan L. Skelton  
Robert A. Schwartzman  
Timothy A. Doyle  
Jennifer R. Mahalingappa

Teresa A. Colella  
Jeffrey S. Lundgren  
Victoria S. Rutherford  
Eric D. Hayes  
**Of Counsel**  
Kenneth C. Bass III  
Evan R. Smith

\*Admitted only in Maryland  
\*Admitted only in Virginia  
•Practice Limited to  
Federal Agencies

October 10, 2003

**WRITER'S DIRECT NUMBER:**  
(202) 772-8589

**INTERNET ADDRESS:**  
LARRYB@SKGF.COM

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**Art Unit To be assigned**

Re: U.S. Utility Patent Application  
Appl. No. 10/602,045; Filed: June 24, 2003  
For: **Molecular Detection Systems Utilizing Reiterative Oligonucleotide Synthesis**  
Inventors: Michelle M. Hanna  
Our Ref: 2072.0010003/LBB/SJE

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Second Supplemental Information Disclosure Statement;
2. Form PTO-1449 (9 sheets citing 31 documents); and
3. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Lawrence B. Bugaiksy  
Attorney for Applicant  
Registration No. 35,086

LBB/SJE/lam  
Enclosures

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Michelle M. HANNA

Appl. No. 10/602,045

Filed: June 24, 2003

For: **Molecular Detection Systems  
Utilizing Reiterative  
Oligonucleotide Synthesis**

Confirmation No. *To be assigned*

Art Unit: *To be assigned*

Examiner: *To be assigned*

Atty. Docket: 2072.0010003/LBB/SJE

**Second Supplemental Information Disclosure Statement**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this Second Supplemental Information Disclosure Statement is a continuation of the numbering in Applicant's First Supplemental Information Disclosure Statement filed on August 12, 2003, in connection with the above-captioned application. Copies of the cited documents were cited by or submitted to the Office in Information Disclosure Statements that comply with 37 C.F.R. § 1.98(a)-(c) in Application No. 09/984,664, filed October 30, 2001, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

The Examiner is referred to the following list of related, co-pending patent applications:

International Application PCT/US02/3419, filed October 29, 2002, which designates the United States and was published in English on May 8, 2003 as WO 03/038942 A2, listed as document **AM1**; and

U.S. Patent Application No. 10/425,037, filed April 29, 2003.

The Examiner is also referred to the following list of related, co-pending patent applications which contain the identical specification as the present application:

U.S. Patent Application No. 09/984,664, filed October 30, 2001;

U.S. Patent Application No. 10/600,581, filed June 23, 2003; and

U.S. Patent Application No. 10/607,136, filed June 27, 2003.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicant has listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Lawrence B. Bugaisky  
Attorney for Applicant  
Registration No. 35,086

Date: October 10, 2003  
1100 New York Avenue, N.W.  
Washington, D.C. 20005-3934  
(202) 371-2600

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FORM PTO-1446  <u>SECOND SUPPLEMENTAL</u> <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 2072.0010003/LBB/SJE	APPLICATION NO. 10/602,045
	APPLICANT Michelle Hanna	
	FILING DATE June 24, 2003	GROUP To be assigned

**U. S. PATENT DOCUMENTS**

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
AA						
AB						
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AD3	5,571,669	11/05/1996	Lu et al.			01/14/1993
AE3	6,251,594 B1	06/26/2001	Gonzalgo et al.			06/09/1998
AF3	2003/0099950 A1	05/29/2003	Hanna, M.M.			10/30/2001
AG						
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**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
AL1	WO 89/01050	02/09/1989	WIPO			Yes No
AM1	WO 03/038042 A2	05/08/2003	WIPO			Yes No
AN						Yes No
AO						Yes No
AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR			
AS	12	Antequerra, F., and Bird, A., "Number of CpG islands and genes in human and mouse," Proc. Natl. Acad. Sci. USA 90:11995-11999, National Academy of Sciences (1993).	
AT	12	Callahan, R., et al., "Frequent Mutations in Breast Cancer," Ann. N.Y. Acad. Sci. 698:21-30, New York Academy of Sciences (1993).	

EXAMINER	DATE CONSIDERED

**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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FORM PTO-1449  SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT		ATTY. DOCKET NO. 2072.0010003/LBB/SJE		APPLICATION NO. 10/602,045	
		APPLICANT Michelle Hanna			
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**FOREIGN PATENT DOCUMENTS**

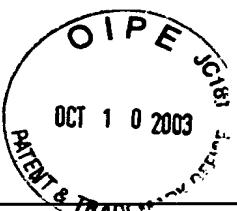
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR	<u>13</u>	Cifone, M.A., and Fidler, I.J., "Increasing metastatic potential is associated with increasing genetic instability of clones isolated from murine neoplasms," <i>Proc. Natl. Acad. Sci. USA</i> 78:6949-6952, National Academy of Sciences (1981).
AS	<u>13</u>	Esteller, M., et al., "Promoter Hypermethylation and BRCA1 Inactivation in Sporadic Breast and Ovarian Tumors," <i>J. Natl. Cancer Inst.</i> 92:564-569, Oxford University Press (April 2000). (Retrieved from LexisNexis Academic database)
AT	<u>13</u>	Frommer, M., et al., "A genomic sequencing protocol that yields a positive display of 5-methylcytosine residues in individual DNA strands," <i>Proc. Natl. Acad. Sci. USA</i> 89:1827-1831, National Academy of Sciences (1992).

EXAMINER	DATE CONSIDERED
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FORM PTO-1449 SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT		ATTY. DOCKET NO. 2072.0010003/LBB/SJE		APPLICATION NO. 10/602,045	
		APPLICANT Michelle Hanna			
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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>14</u>	Giusti, W.G., and Adriano, T., "Synthesis and Characterization of 5'-Fluorescent-dye-labeled Oligonucleotides," <i>PCR Methods Appl.</i> 2:223-227, Cold Spring Harbor Laboratory Press (1993).
AS	<u>14</u>	Gupta, K.C., et al., "A general method for the synthesis of 3'-sulphydryl and phosphate group containing oligonucleotides," <i>Nucleic Acids Res.</i> 19:3019-3025, Oxford University Press (1991).
AT	<u>14</u>	Herman, J.G., et al., "Inactivation of the CDKN2/p16/MTS1 Gene Is Frequently Associated with Aberrant DNA Methylation in All Common Human Cancers," <i>Cancer Res.</i> 55:4525-4530, American Association for Cancer Research (1995).

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	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR	<u>15</u>	Herman, J.G., et al., "Incidence and functional consequences of <i>hMLH1</i> promoter hypermethylation in colorectal carcinoma," <i>Proc. Natl. Acad. Sci. USA</i> 95:6870-6875, National Academy of Sciences (1998).
AS	<u>15</u>	Horii, A., et al., "Frequent Replication Errors at Microsatellite Loci in Tumors of Patients with Multiple Primary Cancers," <i>Cancer Res.</i> 54:3373-3375, American Association for Cancer Research (1994).
AT	<u>15</u>	Issa, J.-P.J., et al., "Methylation of the oestrogen receptor CpG island links ageing and neoplasia in human colon," <i>Nat. Genet.</i> 7:536-540, Nature Publishing Co. (1994).

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AN						Yes No
AO						Yes No
AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>16</u>	Jin, D.J., "An Escherichia coli RNA Polymerase Defective in Transcription due to its Overproduction of Abortive Initiation Products," <i>J. Mol. Biol.</i> 236:72-80, Academic Press Limited (1994).
AS	<u>16</u>	Langer, P.R., et al., "Enzymatic synthesis of biotin-labeled polynucleotides: Novel nucleic acid affinity probes," <i>Proc. Natl. Acad. Sci. USA</i> 78:6633-6637, National Academy of Sciences (1981).
AT	<u>16</u>	Loeb, L.A., "Mutator Phenotype May Be Required for Multistage Carcinogenesis," <i>Cancer Res.</i> 51:3075-3079, American Association for Cancer Research (1991).

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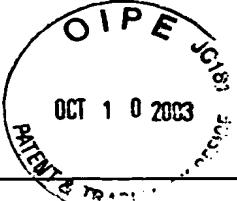
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	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>17</u>	Meinkoth, J., and Wahl, G., "Hybridization of Nucleic Acids Immobilized on Solid Supports," <i>Anal. Biochem.</i> 138:267-284, Academic Press, Inc. (1984).
AS	<u>17</u>	Nowell, P.C., "The Clonal Evolution of Tumor Cell Populations," <i>Science</i> 194:23-28, American Association for the Advancement of Science (1976).
AT	<u>17</u>	Palmisano, W.A., et al., "Predicting Lung Cancer by Detecting Aberrant Promoter Methylation in Sputum," <i>Cancer Res.</i> 60:5954-5958, American Association for Cancer Research (November 2000).

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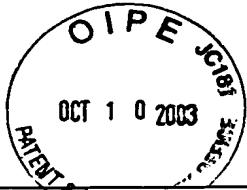
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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>18</u>	Radlowski, M., and Job, D., "Effect of disulfide and sulphydryl reagents on abortive and productive elongation catalyzed by <i>Escherichia coli</i> RNA polymerase," <i>Acta Biochim. Pol.</i> 41:415-419, Panstwowe Wydawnictwo Naukowe (1994).
AS	<u>18</u>	Rice, J.C., et al., "Aberrant methylation of the <i>BRCA1</i> CpG island promoter is associated with decreased <i>BRCA1</i> mRNA in sporadic breast cancer cells," <i>Oncogene</i> 17:1807-1812, Stockton Press (1998).
AT	<u>18</u>	Robertson, K.D., "DNA methylation, methyltransferases, and cancer," <i>Oncogene</i> 20:3139-3155, Nature Publishing Group (May 2001).

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	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>19</u>	Tlsty, T.D., et al., "Differences in the rates of gene amplification in nontumorigenic and tumorigenic cell lines as measured by Luria-Delbrück fluctuation analysis," <i>Proc. Natl. Acad. Sci. USA</i> 86:9441-9445, National Academy of Sciences (1989).
	AS	<u>19</u>	Toyota, M., and Issa, J.-P.J., "CpG island methylator phenotypes in aging and cancer," <i>Semin. Cancer Biol.</i> 9:349-357, Academic Press (1999).
	AT	<u>19</u>	Toyota, M., and Issa, J.-P.J., "The role of DNA hypermethylation in human neoplasia," <i>Electrophoresis</i> 21:329-333, Wiley-VCH Verlag GmbH (January 2000).

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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>20</u>	Vogelstein, B., and Kinzler, K.W., "The multistep nature of cancer," <i>Trends Genet.</i> 9:138-141, Elsevier Science Publishers Ltd. (1993).
AS	<u>20</u>	Wang, J.-Y., et al., "Monovalent cations differ in their effects on transcription initiation from a $\sigma$ -70 promoter of <i>Escherichia coli</i> ," <i>Gene</i> 196:95-98, Elsevier Science B.V. (1997).
AT	<u>20</u>	Wu, D.Y., and Wallace, R.B., "The Ligation Amplification Reaction (LAR) - Amplification of Specific DNA Sequences Using Sequential Rounds of Template-Dependent Ligation," <i>Genomics</i> 4:560-569, Academic Press, Inc. (1989).

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